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Clinical Data from Phase II Study in Early Breast Cancer Suggest Potential Use of Herceptin with New Chemotherapy Combination

-- Additional Study Highlights Importance of HER2 Testing for Metastatic Breast Cancer Patients --

CHICAGO, IL. -- June 2, 2003 -- Genentech, Inc. (NYSE: DNA) today announced initial promising results from a Phase II study evaluating Herceptin® (Trastuzumab) in combination with Navelbine® (vinorelbine) in HER2 (human epidermal growth factor receptor2) positive early-stage breast cancer as well as a second study demonstrating that patients with HER2-positive metastatic breast cancer can respond to treatment with Herceptin and chemotherapy regardless of their estrogen receptor (ER) status. The studies were presented at the annual meeting of the American Society of Clinical Oncology (ASCO).

"This year marks the fifth anniversary of Herceptin's FDA approval, and we continue to be encouraged by results from studying this important targeted therapy in a variety of clinical trials," said Gwen Fyfe, M.D., Genentech's vice president of Clinical Hematology/Oncology. "Data from these studies highlight the breadth of ongoing research that has helped to establish Herceptin as a significant breast cancer treatment."

Herceptin in Combination with Navelbine in Early Breast Cancer (Abstract #86)
This single-arm, Phase II study evaluated the combination of Herceptin and Navelbine as preoperative, neoadjuvant therapy for early-stage HER2-positive breast cancer, followed by mastectomy with post-operative doxorubicin/cyclosphamide (AC) chemotherapy. Lyndsay Harris, M.D. of the Dana-Farber Cancer Institute presented data from the study, which enrolled 40 patients, 28 of whom were evaluable at the time of data analysis. Results from the study demonstrated that 29 percent of the evaluable patients (8/28) experienced a pathologic complete response or the disappearance of all invasive cancer in the breast, which was the study's primary endpoint. In addition, 93 percent of those patients (26/28) experienced a clinical response, or shrinkage of the tumor after treatment with Herceptin and Navelbine.

"This study is important because it showed encouraging responses in women with early-stage HER2-positive breast cancer," continued Dr. Fyfe. "In addition, we continue to study Herceptin in early-stage HER2 breast cancer through the ongoing, randomized Herceptin adjuvant studies, which will provide us with controlled data in this patient population."

The researchers concluded that the combination therapy was well-tolerated in this patient population. One patient discontinued the study after experiencing irregular heartbeats upon receiving AC and two patients experienced asymptomatic Grade 2 cardiac dysfunction. One patient had Grade 3 stomatitis and nausea; no other Grade 3 or 4 events were reported.

Evaluation of ER and HER2 Status (Abstract #179)
A prospective, community-based study is currently ongoing at 294 national sites to evaluate the treatment of Herceptin plus a taxane chemotherapy in HER2-positive metastatic breast cancer patients prospectively selected by fluorescent in-situ hybridization (FISH). FISH testing measures the number of genes in each cell, using fluorescent dye so the HER2 genes can be visualized and counted with a special microscope. More than the normal two HER2 genes per cell are present in HER2 positive breast cancer. Women whose cancer cells contain too many copies of the HER2 gene are candidates for Herceptin therapy.

Pamela Klein, M.D., clinical scientist at Genentech presented data from an analysis of patients enrolled in the study for whom both HER2 and ER status were available. Of the 220 HER2-positive patients with known ER status, 104 patients (47 percent) were ER-positive and 116 patients (53 percent) were ER-negative demonstrating that HER2-positive patients were just as likely to be ER-positive as ER-negative. In addition, the authors concluded that a patient's ER status did not predict the HER2 status of breast cancer tumors.

Of the 220 patients with known HER2 and ER status, 162 patients have been on study at least six months and were evaluable for response: Fifty-six percent (44/79) of the HER2-positive/ER-positive patients had a response, compared to 55 percent (46/83) of patients who were HER2-positive/ER-negative.

"Data from this analysis show that Herceptin in combination with chemotherapy provided clinical benefit to HER2-positive patients, regardless of their ER status," added Dr. Fyfe. "Importantly, this analysis also implies that regardless of the ER status, a HER2 test should be performed to definitively determine whether the patient is HER2-positive and a candidate for Herceptin therapy."

About Herceptin
Herceptin is a targeted therapeutic antibody treatment for women with HER2-positive metastatic breast cancer, an especially aggressive form of the disease that affects approximately one-fourth of women with breast cancer. Special testing is required to identify women who are HER2-positive and candidates for treatment with Herceptin.

Herceptin received FDA approval in September 1998 for use in women with metastatic breast cancer who have tumors that overexpress the HER2 protein. It is indicated for weekly treatment of patients both as first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy. Herceptin is marketed in the United States by Genentech and internationally by F. Hoffmann-LaRoche.

In clinical trials, Herceptin has shown an important survival benefit when used in combination with chemotherapy. In December 2001, Genentech received FDA approval to include data that showed a 24 percent increase in median overall survival for women with HER2 positive metastatic breast cancer treated initially with Herceptin and chemotherapy compared to chemotherapy alone (median 25.1 months compared to 20.3 months).

Herceptin Safety Profile
Herceptin therapy does involve risks. Serious side effects have occurred in patients treated with Herceptin.

Herceptin administration can result in the development of ventricular dysfunction and cardiac failure.

Severe hypersensitivity reactions (including anaphylaxis), infusion reactions, and pulmonary events have been infrequently reported. Rarely, these were fatal. Serious reactions were treated by discontinuing Herceptin and administering supportive therapy. In clinical trials, the incidence and severity of cardiac dysfunction was highest in patients receiving Herceptin with anthracycline and cyclophosphamide (AC). Most patients responded to medical therapy, including discontinuation of Herceptin. However, some patients were successfully managed while continuing Herceptin therapy. Patients receiving Herceptin should be monitored for deteriorating cardiac function.

In clinical trials, approximately 40 percent of patients experienced symptoms such as chills and fever during the first infusion. These and other symptoms, including nausea, vomiting, and pain, occurred infrequently with subsequent infusions. There was an increased incidence of anemia leukopenia, diarrhea, and infection when Herceptin was used in combination with chemotherapy.

Company Background
Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. Fifteen of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes ten biotechnology products in the United States. The company has headquarters in South San Francisco, California and is traded on the New York Stock Exchange under the symbol DNA. For press releases and additional information about the company, please visit http://www.gene.com.

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